

## Message Text

UNCLASSIFIED

PAGE 01 STATE 248391

70

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-10 ISO-00 OES-04 RSC-01 /044 R

66611

DRAFTED BY: DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EUR/WE/WHMARSH

EA/J:CDUNKERLEY

EUR/CE:SGEORGE

ARA/NC:TWSONANDRES

----- 069244

R 112221Z NOV 74

FM SECSTATE WASHDC

TO AMEMBASSY PARIS

AMEMBASSY BONN

AMEMBASSY TOKYO

AMEMBASSY CARACAS

UNCLAS STATE 248391

E.. 11652: NA

TAGS: ETRD, EIND, TBIO, FR, GW, JA, VE

SUBJECT: RECALL OF MEDICAL DEVICE - CARDIAC PACEMAKER.

1. FDA ADVISES THAT THE CORDIS CORPORATION, 125 N.E. 40TH STREET, MIAMI FLORIDA 33137 IS RECALLING THE FOLLOWING: IMPLANTABLE, EXTERNALLY PROGRAMMABLE, CARDIAC PACEMAKERS, OMNI-STANICOR MODEL 162C  
OMNI-ECTOCOR MODEL 163A  
OMNI-ATRICOR MODEL 164  
OMNI-VENTRICOR MODEL 167A

LOT NUMBERS ARE NOT USED. EACH PACER IS IDENTIFIED BY THE MODEL NUMBER FOLLOWED BY THE SERIAL NUMBER. BETWEEN DECEMBER 1972 AND MARCH 1974, THE FOLLOWING UNITS WERE MANUFACTURED AND IMPLANTED:

OMNI-STANICOR 3,000

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 248391

OMNI-ECTOCOR 600

OMNI-ATRICOR        600  
OMNI-VENTRICOR     600

AT LEAST 200 OF THE UNITS ARE SUSPECT SINCE THEY CONTAIN FAULTY DELTA AND ALPHA DECODERS WHICH ARE BOTH COMPONENTS OF THE OMNI SERIES OF THE PACERS. SHORT CIRCUITS WITHIN THE SEALED UNITS CAUSE A PREMATURE GRADUAL DEPLETION OF THE PACER BATTERIES. THE PACERS ARE WARRANTED FOR THREE YEARS BUT FAILURE HAS OCCURRED WITHIN SIX TO EIGHTEEN MONTHS. FOUR PATIENTS HAVE EXPIRED; HOWEVER THE FIRM CLAIMS THAT THE ATTENDING PHYSICIANS DO NOT ATTRIBUTE DEATHS TO THE PACER MALFUNCTION.

2. FOREIGN DISTRIBUTION CURRENTLY AVAILABLE IS AS FOLLOWS:

DR. PIOGER, CLINIC DE L'AUDE, PARIS FRANCE, MODEL OMNI-STANICOR 162C SERIAL NO. 487 WITH DELTA 316B, SERIAL NO. 35.

DR. BONNET, SEDANTON, PARIS, FRANCE, OMNI-STANICOR MODEL 162C, SERIAL NO. 399 WITH DELTA 316B, SERIAL NO. 12. THIS UNIT WAS IMPLANTED IN MAY 23, 1973 AND WAS EXPLANTED DEC. 1973.

DR. STAUCH, UNIVERSITAT HOSPITAL, ULM, WEST GERMANY, OMNI-STANICOR MODEL 162C, SERIAL NO. 483 WITH DELTA 316B, SERIAL NO. 18. THIS UNIT WAS IMPLANTED ON SEPT. 11, 1973 AND WAS EXPLANTED FEB. 1974.

DR. MACHII, MITUSI, MEMORIAL HOSPITAL, TOKYO, JAPAN, OMNI-STANICOR MODEL 162C, SERIAL NO. 481 WITH DELTA 316B, SERIAL NO. 5. THIS UNIT WAS IMPLANTED ON JUNE 28, 1973 AND WAS EXPLANTED JAN. 1974.

DR. O. HERNANDEZ, CLINICA RAJETTI, CARACAS, VENEZUELA, OMNI-STANICOR MODEL 162C, SERIAL NO. 485 WITH DELTA 316B, SERIAL NO. 19. THIS UNIT WAS IMPLANTED APRIL 6, 1973.

3. POSTS ARE REQUESTED TO ASCERTAIN WHETHER FOREIGN CONSIGNEES ARE FAMILIAR WITH DETAILS OR RECALL AND TO VERIFY WHETHER PACEMAKERS STATED TO BE EXPLANTED WERE ACTUALLY REMOVED.  
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 248391

KISSINGER

UNCLASSIFIED

NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 11 NOV 1974  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1974STATE248391  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** DHEW/FDA/JRWEINROTH, M.D.  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D740325-0244  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1974/newtext/t19741153/aaaabsqq.tel  
**Line Count:** 108  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 2  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** elyme  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 15 OCT 2002  
**Review Event:**  
**Review Exemptions:** n/a  
**Review History:** RELEASED <15 OCT 2002 by maustmc>; APPROVED <12 FEB 2003 by elyme>  
**Review Markings:**

Declassified/Released  
US Department of State  
EO Systematic Review  
30 JUN 2005

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** RECALL OF MEDICAL DEVICE - CARDIAC PACEMAKER.  
**TAGS:** ETRD, EIND, TBIO, FR, GE, JA, VE  
**To:** PARIS MULTIPLE  
**Type:** TE  
**Markings:** Declassified/Released US Department of State EO Systematic Review 30 JUN 2005